

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ann-Margret Andersson, et al  
Serial No. : 10/715,903  
Filed : November 18, 2003  
Title: ANTIMICROBIAL LENSES, PROCESSES TO PREPARE THEM  
AND METHODS OF THEIR USE  
Art Unit : 1713  
Examiner : Hu, Henry S.

Honorable Commissioner of Patents  
Alexandria, VA 22313

DECLARATION UNDER 37 CFR 1.132

I, Douglas Vanderlaan, PhD, declare as follows:

1.1 I am currently a Senior Scientist for Johnson & Johnson Vision Care, Inc. I received a Bachelor of Science in Chemistry from Calvin College, in 1979, and a Doctorate in Organic Chemistry from Florida State University in 1984. I was a research fellow in the field of Organic Chemistry at the University of Michigan from 1984-1985. I was a Research Chemist at SWS Silicones from 1985-1986 and Senior Chemist at Reichhold Chemicals from 1986-1989. I have been a scientist for Johnson & Johnson Vision Care, Inc since 1989. In my tenure with Johnson & Johnson Vision Care, Inc. I have been engaged in research and study of materials for contact lenses.

1.2 I reviewed the Example of US 4,576,453 ("Borowsky") and repeated the Borowsky lenses as follows.

1.3 Borowsky did not disclose what lenses were used. I selected commercially available lenses, ACUVUE 2 brand contact lenses.

1.4 Six ACUVUE 2 lenses were removed from their packages, blotted to remove surface water, and floated on a 1% (wt) solution of sodium chloride (0.15% NaCl added

to packing solution containing 0.85% NaCl). A drop of 1% AgNO<sub>3</sub> (in deionized water) was placed into the concave center of each lens, and allowed to sit for about 5 minutes. The lenses were rinsed with water, then exposed to both beams of light from a Techni-Quip Corp. fiber optic light for 20 minutes, during which time the center region of each lens developed a dark gray color. The lenses were washed with deionized water and placed into "Standard Fixer", as described in Borowsky for 75 minutes. :

Component	Wt. %
Sodium thiosulfate	24
Sodium sulfate	1.5
Acetic acid	1.34
Boric acid	0.75
potassium alum in water	1.5

1.5 After treatment with Standard Fixer the lenses were very stiff.

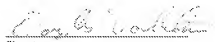
1.6 The lenses were then washed with deionized water, and boiled for two hours in borate buffered ophthalmic saline. The flexibility of the lenses was restored. The lenses were placed into a solution of 0.01% (wt.) gold chloride in Standard Fixer for two days, then boiled in borate buffered saline for two hours again. Finally the lenses were placed into glass vials and autoclaved at 121°C for 30 minutes.

1.6 The antimicrobial efficacy of the lenses produced above was tested following the procedure of Example 12 in US Serial No. 10/715,903. The lenses did not show a reduction of viable bacteria of more than 0.5 log.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereof.

Declarant's Full Name

Douglas Vanderlaan, PhD

  
Signature

December 1, 2006